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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Shiau et al. Confirmation No.: 9894

Serial No.: 09/830,693 Art Unit: 1646

Filed: March 30, 1999 (§ 371 date: January 29, 2002) Examiner: Zeman, Mary

For: METHODS AND COMPOUNDS FOR MODULATING NUCLEAR RECEPTOR ACTIVITY Attorney Docket No.: 9811-013-999

## INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

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Sir:

In accordance with the duty of disclosure provisions of 37 C.F.R. §1.56, there is hereby provided certain information which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

1. Enclosures accompanying this Information Disclosure Statement are:
  - 1a. ☒ A list of all patents, publications, applications, or other information submitted for consideration by the office.
  - 1b. A legible copy of :
    - ☐ Each U.S. patent application publication and U.S. and foreign patent;
    - ☒ Each publication or that portion which caused it to be listed on the PTO-1449;
    - ☐ For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or portion of the application which caused it to be listed on the PTO-1449 including any claims directed to that portion;
    - ☐ all other information or portion which caused it to be listed on the PTO-1449.
  - 1c. ☐ An English language copy of search report(s) from a counterpart foreign application or PCT International Search Report.
  - 1d. ☐ Explanations of relevancy (ATTACHMENT 1(d), hereto) or English language abstracts of the non-English language publications.
2. ☒ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b):
  - ☐ Within three months of the filing date of a national application other than a continued prosecution application under §1.53(d);
  - ☐ Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;

- ☒ Before the mailing of the first Office action on the merits;
- ☐ Before the mailing of a first Office action after the filing of a request for continued examination under §1.114.

3. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the period specified in 37 C.F.R. §1.97(b), but before the mailing date of any of a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311 or an action that otherwise closes prosecution in the application.

*(Check either Item 3a or 3b)*

- 3a. ☐ The Certification Statement in Item 5 below is applicable. Accordingly, no fee is required.
- 3b. ☐ The \$180.00 fee set forth in 37 C.F.R. §1.17(p) in accordance with 37 C.F.R. §1.97(c) is:
- ☐ enclosed
- ☐ to be charged to Pennie & Edmonds LLP Deposit Account No. 16-1150.

*(Item 3b to be checked if any reference known for more than 3 months)*

4. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(d) after the period specified in 37 C.F.R. §1.97(c), but on or before the date of payment of the issue fee.

The \$180.00 fee set forth in 37 C.F.R. §1.17(p) is:

- ☐ enclosed.
- ☐ to be charged to Pennie & Edmonds LLP Deposit Account No. 16-1150.

The Certification Statement in Item 5 below is applicable.

5. ☐ Certification Statement (applicable if Item 3a or Item 4 is checked)

*(Check either Item 5a or 5b)*

- 5a. ☐ In accordance with 37 C.F.R. §1.97(e)(1), it is certified that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- 5b. ☐ In accordance with 37 C.F.R. §1.97(e)(2), it is certified that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was known by any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.
6. ☐ This application is a continuation application under 37 C.F.R. §1.60 or §1.53(b) or (d).

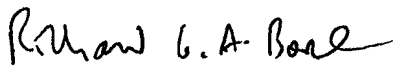
*(Check appropriate Items 6a, 6b and/or 6c)*

- 6a. ☐ A Petition to Withdraw from issue under 37 C.F.R. §1.313(b)(5) is concurrently filed herewith.

- 6b. ☐ Copies of publications listed on Form PTO-1449 from prior application Serial No. , filed on , of which this application claims priority under 35 U.S.C. §120, are not being submitted pursuant to 37 C.F.R. §1.98(d).
- 6c. ☐ Copies of the publications listed on Form PTO-1449 were not previously cited in prior application Serial No. , filed on , and are provided herewith.
7. ☒ This is a Supplemental Information Disclosure Statement. (Check Item 7a)
- 7a. ☒ This Supplemental Information Disclosure Statement under 37 C.F.R. §1.97(f) supplements the Information Disclosure Statement filed on January 28, 2003. A bona fide attempt was made to comply with 37 C.F.R. §1.98, but inadvertent omissions were made. These omissions have been corrected herein. Accordingly, additional time is requested so that this Supplemental Information Disclosure Statement can be considered as if properly filed on January 28, 2003.
8. ☐ In accordance with 37 C.F.R. §1.98, a concise explanation of what is presently understood to be the relevance of each non-English language publication is:
- ( Check Item 8a, 8b, or 8c)
- 8a. ☐ satisfied because all non-English language publications were cited on the enclosed English language copy of the PCT International Search Report or the search report from a counterpart foreign application indicating the degree of relevance found by the foreign office.
- 8b. ☐ set forth in the application.
- 8c. ☐ enclosed as an attachment hereto.
9. ☒ The Commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement and/or Petition to Pennie & Edmonds LLP Deposit Account No. 16-1150.
10. ☒ No admission is made that the information cited in this Statement is, or is considered to be, material to patentability nor a representation that a search has been made (other than a search report of a foreign counterpart application or PCT International Search Report if submitted herewith). 37 C.F.R. §§1.97(g) and (h).

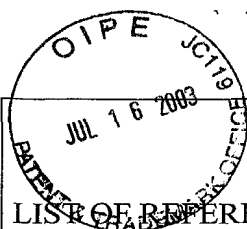
Respectfully submitted,

Date: July 16, 2003



Richard G. A. Bone  
Limited Recognition Under 37 C.F.R. § 10.9(b)  
(Copy of Certificate attached hereto)

for Samuel B. Abrams · Reg. No. 30,605  
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# LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)

ATTY DOCKET NO.

9811-013-999

APPLICATION NO

09/830,693

APPLICANT

Shiau, et al.

FILING DATE

3/30/99 (§ 371 date, 01/29/02)

GROUP

1646

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

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## FOREIGN PATENT DOCUMENTS

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DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
					YES NO

## OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

EG	Stephen E. Fawell, et al., "Characterization and Colocalization of Steroid Binding and Dimerization Activities in the Mouse Estrogen Receptor", Cell, Vol. 60, March 23, 1990, 953-962.
EH	David F. V. Lewis, "Molecular Modelling of the Human Estrogen Receptor and Ligand Interactions Based on Site-directed Mutagenesis and Amino Acid Sequence Homology", J. Steroid Biochem. Molec. Biol., Vol. 52, No. 1, 1995, 55-65.
EI	Lester F. Harris, et al., "Molecular Dynamics Simulation in Solvent of the Estrogen Receptor Protein DNA Binding Domain in Complex with a Non-Consensus Estrogen Response Element DNA Sequence", Journal of Biomolecular Structure & Dynamics, Vol. 15, Number 3, 1997, 407-430.
EJ	George J. Maalouf, "Homology Model for the Ligand-Binding Domain of the Human Estrogen Receptor", Journal of Biomolecular Structure & Dynamics, Vol. 15, Number 5, 1998, 841-851.
EK	John W. R. Schwabe, et al., "The Crystal Structure of the Estrogen Receptor DNA-Binding Domain Bound to DNA: How Receptors Discriminate between Their Response Elements", Cell, Vol. 75, November 5, 1993, 567-578.
EL	John W. R. Schwabe, et al., "The oestrogen receptor recognizes an imperfectly palindromic response element through an alternative side-chain conformation", Structure, Vol. 3, 15 February, 1995, 201-213.
EM	H. Ewa Witkowska, et al., "Characterization of bacterially expressed rat estrogen receptor $\beta$ ligand binding domain by mass spectrometry: Structural comparison with estrogen receptor $\alpha$ ", Steroids, 1997, 62:621-631.
EN	Jean-Marie Wurtz, et al., "Three-Dimensional Models of Estrogen Receptor Ligand Binding Domain Complexes, Based on Related Crystal Structures and Mutational Structure-Activity Relationship Data", J. Med. Chem., 1998, 41, 1803-1814.

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



**BEFORE THE OFFICE OF ENROLLMENT AND DISCIPLINE  
UNITED STATE PATENT AND TRADEMARK OFFICE**

**LIMITED RECOGNITION UNDER 37 CFR § 10.9(b)**

Dr. Richard G. A. Bone is hereby given limited recognition under 37 CFR §10.9(b) as an employee of Pennie & Edmonds, LLP to prepare and prosecute patent applications wherein the patent applicant is the client of Pennie & Edmonds, LLP, and the attorney or agent of record in the applications is a registered practitioner who is a member of Pennie & Edmonds, LLP. This limited recognition shall expire on the date appearing below, or when whichever of the following events first occurs prior to the date appearing below: (i) Dr. Richard G. A. Bone ceases to lawfully reside in the United States, (ii) Dr. Richard G. A. Bone's employment with Pennie & Edmonds, LLP ceases or is terminated, or (iii) Dr. Richard G. A. Bone ceases to remain or reside in the United States on an H-1B visa.

This document constitutes proof of such recognition. The original of this document is on file in the Office of Enrollment and Discipline of the U.S. Patent and Trademark Office.

**Expires: March 27, 2004**

Harry I. Moatz  
Director of Enrollment and Discipline

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